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s ⁻	TATEMENT B	BY APPERCIAN		First Named Inventor	Fitzhugh et al.
				Group Art Unit	1616
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Sheet	2	of	3	Attorney Docket Number	17363-20

156	5837313	11/17/1998	Ding et al.	
1	5837736	11/17/1998	Mitchell et al.	
	5840759	11/24/1998	Mitchell et al.	
	5877216	03/02/1999	Place et al.	
	5891459	04/06/1999	Cooke et al.	
	5910316	06/08/1999	Keefer et al.	
	5945452	08/31/1999	Cooke et al.	
- -	5958427	09/28/1999	Salzman et al.	
	5962520	10/05/1999	Smith et al.	
	5994444	11/30/1999	Trescony et al.	
MA	6024918	02/15/2000	Hendriks et al.	7

				FC	DREIGN PATENT DOCUMENTS	3		
0		For	eign Patent Docu	ment			Pages, Columns, Lines,	7-8
Examiner Initials	Cite No.¹	Office ³	Number ⁴	Kind Code	Name of Patentee or Applicant of Cited Document	Date of Publications of Cited Documents MM/DD/YYYY	Where Relevant Passages or Relevant Figures Appear	
166		wo	00/02501		William Harvey Research LTD.	01/20/00		

		OTHER PRIOR ART / NON PATENT LITERATURE DOCUMENTS						
Examiner Initials'	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the ltem (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume/issue number(s), publisher, city and/or country where published.	T ²					
BF		uer et al.; Evaluation of Linear Polyethyleneimine/nitric Oxide Adduct on Wound Repair: Therapy versus xicity; Wound Repair & Regeneration, November/December 1998, pp. 569/577						
		Chandy et al; "Use of Plasma Glow for Surface/Engineering Biomolecules to Enhance Bloodcompatibility of Dacron and PTFE Vascular Prosthesis." Biomaterials 21: 699/712						
	В	Drago; "Free Radicals in Inorganic Chemistry." No. 36, Advances in Chemistry Series, American chemical society, Washington, D. C. 1962, pp. 143/149						
		Hanson et al; Nitric Oxide Donors: A Continuing Opportunity in Drug Design; Advances in Pharmacology, Vol 34, pp. 383/398						
		Hrabie et al; "New Nitric Oxide/Releasing Zwitterions Derived from Polyamines." J. Org. Chem. 1993, 58, 1472/1476						
bo		Jordi; Jordi Gel Columns for Size Exclusion Chromatography; Column Handbook for Size Exclusion Chromatography; 1999, pp. 367/425						
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ST	ATEMENT B	YMPPHICAN	IT	First Named Inventor	Fitzhugh et al.	
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Sheet	1	of	3	Attorney Docket Number	17363-20	

		U.S. Patent	Document	Date of Publications of Cited	Name of Patentee or	Pages, Columns, Lines, Where
Examiner Initials	Cite No. ¹	Number	Kind Code ²	Documents MM-DD-YYYY	Applicant of Cited Document	Relevant Passages or Relevant Figures Appear
BF		4954526	1	09/04/1990	Keefer	
0		5039705		08/13/1991	Keefer et al.	1
		5155137		10/13/1992	Keefer et al.	/
		5171217		12/15/1992	March et al.	
-		5212204		05/18/1993	Keefer et al.	/
		5229172	 	07/20/1993	Cahalan et al.	
		5250550		10/05/1993	Keefer et al.	
		5268465		12/07/1993	Bredt et al.	
		5366997		11/22/1994	Keefer et al.	
		5380758		01/10/1995	Stamler et al.	
		5405919		04/11/1995	Keefer et al.	/
		5428070	<u> </u>	06/27/1995	Cooke et al.	
		5468630	<u> </u>	11/21/1995	Billiar et al.	
		5482925		01/09/1996	Hutsell	
		5519020		05/21/1996	Smith et al.	
		5525357		06/11/1996	Keefer et al.	
		5574068		11/12/1996	Stamler et al.	/
		5583101		12/10/1996	Stamler et al.	
		5632981		05/27/1997	Saavedra et al.	
•		5650447	·····	07/22/1997	Keefer et al.	
		5658565		08/19/1997	Billiar et al.	
		5676963	 	10/14/1997	Keefer et al.	
		5683668		11/04/1997	Hrabie et al.	
		5691423		11/25/1997	Smith et al.	
	1	5700830		12/23/1997	Korthuis et al.	
		5714511		02/03/1998	Saavedra et al.	
		5718892		02/17/1998	Keefer et al.	
		5721365	1	02/24/1998	Keefer et al.	
	<u> </u>	5770645		06/23/1998	Stamler et al.	1/
		5789447		08/04/1998	Wink, Jr. et al.	1/
	 	5814656		09/29/1998	Saavedra et al.	/
BC	 	5814667		09/29/1998	Mitchell et al.	1
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S	TATEMENT	BY APPÉ@A	NAME	First Named Inventor	Fitzhugh et al.
				Group Art Unit	1616
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Sheet	3	of	3	Attorney Docket Number	17363-20

BE	Kaul et al.; Polymeric/Based Perivascular Delivery of a Nitric Oxide Donor Inhibits Intimal Thicening After Balloon Denudation Arterial Injury: Role of Nuclear Factor/kappaB; Journal of the American College of Cardiology, Vol. 35, No. 2, 2000:493/501	
1.	Keefer et al; "NONOates" (1/Substituted Diazen/1/ium/1,2/diolates) as Nitric Oxide Donors: Convenient Nitric Oxide Dosage Forms." Methods in Enzymology, Vol 268: 281/293	
	Mowery et al.; Preparation and Characterization of Hydrophobic Polymeric Films That Are Thromboresistant Via Nitric Oxide Release; Biomaterials 21 (2000) 9/21	
	Saavedra et al.; "Conversion of Polysaccharide to Nitric Oxide/Releasing Form Dual/Mechanism Anticoagulant Activity of Diasenium diolated Heparin." Bioorganic & Medicinal Chemistry Letters 10 (2000) 1/3	
bil	Smith et al.; Nitric Oxide/Releasing Polymers Containing the [N(O)NO]' Group; J. Med. Chem. 1996, 39, 1148/1156	

Examiner Signature	Blessing	Fubna	Date Considered	12/12/04
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Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number. le for form 1449A/PTO Complete if Known **Application Number** 10/623,239 **Filing Date** INFORMATION DISCLOSURE 7/17/2003 First Named Inventor STATEMENT BY APPLICANT Fitzhugh et al. **Group Art Unit** 1616 Unassigned **Examiner Name** (use as many sheets as necessary) P497 CON 1 (14364-0099) **Attorney Docket Number** Sheet of **U.S. PATENT DOCUMENTS** Name of Patentee or Pages, Columns, Lines, Where **Document Number Publication Date** Relevant Passages or Relevant Examiner Cite MM-DD-YYYY **Applicant of Cited** No.1 Number-Kind Code^{2 (If known)} Initials Figures Appear Document

				FORE	GN PATENT DOCUMENTS			
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51		wo	0030658	A1	Smith et al.	06/02/2000]

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS							
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposlum, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²				
BF		Downey et al.; Growth Mechanism of Poly(divinylbenzene) Microspheres in Precipitation Polymerization; American Chemical Society, Easton, US, Vol. 32, No. 4, 4 May 1999; pgs 2838-2844					
Bas		Pulfer et al.; Incorporation of Nitric Oxide-Releasing Crosslinked Polyethyleneimine Microspheres Into Vascular Grafts; Journal of Biomedical Materials Research; Wiley, New York, NY, Vol. 37, No. 2, November 1997 (1997-11); pp. 182-189					
POF		Zhang et al.; Synthesis of Nitric Oxide Releasing Silicone Rubbers for Biomedical Applications; Polymer Preprints; Vol. 40, No. 2, 1999, pgs 799-800					

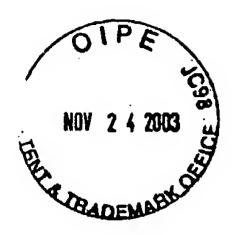
				
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	AO	WO 1/58435 A1	8/16/01	WIPO	•				
	AP	0 183 436 A2	11/13/85	EPO					
	AQ	H10-25245	1/27/98	JAPAN					
	AR	H11-343497	12/14/99	JAPAN					
	AS	H4-128234	4/28/92	JAPAN					
	AT	H6-40911	2/15/94	JAPAN					
	ΑU	H5-255688	10/5/93	JAPAN					
	AV	2000-42125	2/15/00	JAPAN					
	AW	H10-113369	5/6/98	JAPAN					
\		OTHER RE	FERENCES (ncluding Author, Title, Date, Pertiner	nt Pages. et	tc.)			
h			<u> </u>				EKINE, Emotion		
AT !	AX	Toshimitsu MUSHA, Ph.D., Shin KIMURA, M.S., Ken-Ichi KANEKO, Kiyoka NISHIDA, and Kazuo DEKINE, Emotion Spectrum Analysis Method (ESAM) for Monitoring the Effects of Art Therapy Applied on Demented Patients,							
		CybrPsychology & Behavior, Vol. 3, No. 3, 2000, pp. 441-446, Mary Ann Liebert, Inc. Kazuhiko SAWADA, Ryoichi KOMAKI, Yoshikuni YAMASHITA, Yasushi SUZUKI and Selichi ISHIYAMA, Physiological							
	AY	Effects of Volatile Components in Forest, Kanebo Co. Ltd. Cosmetic Laboratory and Research Institute of Human							
	AZ	Engineering for Quality Lifge, Odawara 250-0002. A Manual of Standardized Terminology, Techniques and Scoring System for Sleep Stages of Human Subjects; Allan Rechtschaffen, et al., 1968.							
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LIST OF REFERENCES CITED BY APPLICANT			Yoshinao NAGASHIMA, et al.					
			FILING DATE	GROUP				
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			Application No. JP 96182349, January 27, 1998, "Oral Hypnotic Agent used for s Contain Essential Oil of Sandalwood."					
	AAB	Abstract, Patent No. JP 11343497, Application No. JP 98188008, December 14, 1999, "Cosmetics Showing Sedative and Hypnotic Effect Comprising Flavour of Rosemary, Lavendar, Bitter Orange or Senkyu."						
	AAC	Abstract, Patent No. JP 4128234, Application No. JP 90249716, April 28, 1992, "New Sleep Promoting Agent Comprising Bitter Orange Essential Oil, Formulated for Absorption through the Nasal Mucosa or the Lungs."						
	AAD	Abstract, Patent No. JP 6040911, February 16, 1994, Application No. JP 92195333, July 22, 1992, "Sleep Promoter Containing Jasmine Lactone as Active Component is in the Form of Preparation where Active Component is Absorbed from Lung or Nose or Mouth Mucosa."						
	AAE	Abstract, Patent No. JP 5255688, October 5, 1993, Application No. JP 9289811, March 13, 1992, "Perfume Containing Sedative Essential Oil has Durable Sedative Effect."						
	AAF	Abstract, Patent No. JP 10113369, May 6, 1998, Application No. 9770225, March 24, 1997, (WO 9807403), "Cosmetological Method for Achieving Valuable Cosmetic Effects Easily by Massage Comprising Massage Carried Out by Oridinary People Along Arterial and then Venous Blood Flow Paths using Cosmetic Containing Disintegrative Particles."						
j	AAG	Sawada, et al., 132CA:332157, 1999	•	·				
V	AAH	Binet, et al., 78CA:24110, 1972.						
	AAI							
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LIST OF RELATED CASES

Docket Number	Serial or Patent Number	Issue Date	Inventor/ Applicant
240950US0-DIV	10/646,825	08/25/03	NAGASHIMA, et al.
240945US0-DIV* -	10/645,554	08/22/03	NAGASHIMA,

Channavajzele

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